

REMARKS

Claims 1-37 are pending in the subject application. Applicants respectfully request reconsideration of the subject application in view of the following remarks.

I. Rejection Under the Judicially Created Doctrine of Obvious-Type Double Patenting

On page 4 of the Office Action the Examiner maintained her rejection of claims 1-37 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 9, compounds 1 and 2, claims 10-23 of U.S. Patent No. 6,235,764 ("the '764 patent"). The Examiner further states that the alleged conflicting claims are not identical, they are not patentably distinct from each other. The Examiner notes that the instant claims are drawn to various salts of 3-(4-bromo-2,6-difluoro-benzyloxy-5-[3-(4-pyrrolidin-1-yl)-butyl]-ureido]-isothiazole-4-carboxylic acid amide, pharmaceutical compositions and method of using same. The Examiner states that the difference between the claimed salts and the reference is that the instant claims are to specific salts of the compounds that are not claimed. The Examiner points applicants' to claim 10 of the '764 patent and the list of various salts that can be made, citing, column 11, lines 38-50. The Examiner concludes that one of ordinary skill in the art would be motivated to make additional salt forms of this known compound with the specific suggestion and teaching that the reference provides that the claimed salt form can be made.

Applicants respectfully continue to traverse the Examiner's obviousness-type double patenting rejection of the claims 1-37 of the instant application over the '764 patent for the reasons of record from their February 3, 2003 Communication in response to the Examiners October 3, 2002 Office Action and the following additional reasons set forth below. Although, Applicants have not recited verbatim the remarks from their February 3, 2003 Communication they nevertheless maintain that it set forth in detail the standards applicable to a finding of obviousness-type double patenting.

Applicants note initially that double patenting is concerned with attempts to claim the same or related subject matter twice. *Chisum on Patents*, §9.03[1][a]. Thus, the standard for comparison for the second patent is what is claimed in the first patent, not what was disclosed in the specification of the first patent. *Id.* With that in mind, applicants now

turn to the Examiner's remarks in response to applicants' first office action Communication that was mailed on February 3, 2003 and received by the Examiner on February 20, 2003.

On page 2 of the Office Action the Examiner provided remarks in response to applicants' February 3, 2003 Communication in response to the Office Action dated October 3, 2002. In particular, the Examiner disagrees with applicants' assertion that the "Examiner is using the '764 patent as prior art" and further states that applicants' "suggests that the only instance where the patent disclosure may be used in a double patenting rejection is in the form of a dictionary to understand the meaning of terms employed in the claims."

The Examiner cites *in re Boylan* for the proposition that the specification can always be used as a dictionary to learn the meaning of a term in a patent claim. The Examiner cites *in re Vogel* for the proposition that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention in the patent.

The Examiner asserts that the '764 patent is not being employed as prior art, "rather it is being relied on where it provides support for obvious variations of the patent claim". The Examiner states that "[c]laims 9-23 in the '764 patent recite specifically the compounds instantly claimed and their pharmaceutically acceptable salts. The portion of the '764 patent specification, column 11, lines 38-50, relied on in the previous office action provides support for the 'pharmaceutically acceptable salts' variations of the claimed invention and thus may be considered. The Examiner concludes the use of the '764 disclosure "is proper and supports the double patenting rejection".

Applicants respectfully submit that the Examiner is using the '764 patent as prior art to the instant claims, which is improper, as stated in *re Vogel*. The Examiner may in certain instances use the disclosure of a cited patent in an obviousness-type double patenting rejection as a dictionary to learn the meaning of a term in a claim. However, one of the primary rules of claim construction is that claim terms are given their ordinary meaning as one skilled in the art would understand them unless it appears from the specification that the terms were used differently by the inventors. *Envirotech Corp. v. Al. George, Inc.*, 221 USPQ 473, 477 (Fed. Cir. 1984). In the absence of an indication in the specification that a term is used in a unique or special way, it will be given its ordinarily understood meaning. *Hazani v. United States Int'l Trade Comm'n*, 44 USPQ2d 1359 (Fed. Cir. 1997). Applicants

respectfully submit that the terms of the claims of the '764 patent are clear on their face and do not require the Examiner's examination of the specification of the '764 patent.

Applicants respectfully submit that there is nothing unique or special about the use of the term "pharmaceutically acceptable salts" in the '764 patent. This is a well-understood term of art in the pharmaceutical arts. It is so well understood that those of ordinary skill in the art have no need to refer to the specification to understand what "pharmaceutically acceptable salts" means. However, the Examiner in the instant application proceeds directly to the specification to gain an understanding of a term that is used in most, *if not every*, pharmaceutical patent application submitted for examination to the United States Patent Office. Applicants respectfully submit that recourse to the specification to understand a term so well understood by those of ordinary skill in the art is not necessary. The Examiner is not giving the claims their ordinary meaning.

Furthermore, applicants respectfully submit that the Examiner is trying to import a limitation from the specification in the claims of the '764 patent. The courts have repeatedly held that a limitation from the specification will generally not be read into a claim. Additionally, in general, a claim term will not be construed as being limited to what is shown in a preferred embodiment or specific working example in a specification absent evidence in the prosecution history showing such to be the case. *Ekchian v. Home Depot Inc.*, 41 USPQ2d 1364 (Fed. Cir. 1997).

As noted above the Examiner cites column 11, lines 38-50, as providing support for the "pharmaceutically acceptable salts" language in the claims of the '764 patent. Applicants respectfully submit that there is no need to review the language of the specification to understand a well-understood term of art "pharmaceutically acceptable salts". Furthermore, use of the language from the specification in column 11, lines 38-50 cannot be applied by the Examiner to limit in any way the use of the term "pharmaceutically acceptable salts" in the '764 patent. Applicants respectfully submit that the claims of the instant application are not an obvious variation of the issued claims of the '764 patent.

Applicants respectfully submit that the claims of the '764 patent claim the mesylate and hydrochloride salt of the 3-(4-bromo-2,6-difluorobenzyloxy-5-[3-(4-pyrrolidin-1-yl)-butyl]-ureido]-isothiazole-4-carboxylic acid amide. The claims of the present invention are directed to a distinct set of salts from that of the '764 patent.

On page 3 of the current Office Action the Examiner in her remarks asserts that there is ample motivation and suggestion provided in the '764 patent, citing, column 11, lines 38-50 as providing

“obvious variations of the claimed invention, i.e., the pharmaceutically acceptable salts of the claimed compounds, especially those that are preferred. Thus, one of ordinary skill in the art would be motivated to make additional pharmaceutically acceptable salts of the compounds claimed in the '764 patent as the patent specifically indicates the preferred pharmaceutically acceptable salts embodiments of the compounds, consequently providing a reasonable expectation of success in the end utility of said compound.”

The Examiner is making an unsupported assumption that one of ordinary skill in the art would be motivated to make the instant compounds on the basis of the claims of the '764 patent and the disclosure of salts in column 11, lines 38-50. As stated hereinabove the Examiner is improperly accessing the disclosure in column 11, lines 38-50 and trying to fashion a motivation argument. Even if one assumes for the sake of argument that the Examiner properly refers to the disclosure for the meaning of the term “pharmaceutically acceptable salts”, which the Examiner cannot, there is no teaching or suggestion in the '764 patent to lead one to make the claimed compounds. In fact, the specifications as well as the claims of the '764 patent define a large number of suitable pharmaceutically acceptable salts.

Where is one of ordinary skill in the art to start? How does one of ordinary skill in the art know based upon the claims of the '764 patent that the instant compounds would be desirable? The Examiner is trying to match up the claimed instant compounds to compounds in the specification of the '764 patent. Such an exercise, while improper, still does not teach or suggest to one of ordinary skill in the art to make the instant compounds. Why is the Examiner preferring to select some salts from those disclosed in the '764 patent while ignoring a large number of number of additionally disclosed salts?

Obviousness cannot be established by hindsight combination to produce the claimed invention or in view of the teachings or suggestions of the inventor. *In re Dance*, 48

U.S.P.Q.2d 1635 (Fed. Cir. 1998); *In re Gorman*, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 311, 312-13 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination. *In re Dance*, 48 U.S.P.Q.2d 1635 (Fed. Cir. 1998); *Interconnect Planning Corp. v. Feil*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). Additionally, when determining obviousness, the claimed invention should be considered as a whole; there is no legally recognizable "heart" of the invention. *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 309 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

The Examiner is trying to provide the motivation to make the claimed invention by using an improper standard of *obvious to try*. Courts have long held that "obvious to try" does not constitute obviousness. *In re O'Farrell*, 7 U.S.P.Q.2d 1673, 1680-81 (Fed. Cir. 1988); *In re Geiger*, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987); *In re Goodwin*, 198 U.S.P.Q. 1, 3 (C.C.P.A. 1978); *In re Antonie*, 195 U.S.P.Q. 6, 8 (C.C.P.A. 1977); *In re Lindell*, 155 U.S.P.Q. 521, 523 (C.C.P.A. 1967); *In re Tomlinson*, 150 U.S.P.Q. 623 (C.C.P.A. 1966); *In re Papesch*, 137 U.S.P.Q. 43 (C.C.P.A. 1963).

Applicants respectfully submit that based upon the claims of the '764 patent when given their ordinary meaning provides for a multitude of salts that would satisfy the term "pharmaceutically acceptable salts". Nevertheless, the Examiner is able to divine the necessary motivation to identify applicants particular salts even in the face of the large number of choices embraced by the term "pharmaceutically acceptable salts". Although, a number of particular salts, the mesylate and HCl, are claimed in the '764 patent, these do not help to provide the motivation to arrive at the instant invention.

The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of patent for the same invention or an obvious modification thereof. *In re Longi*, 225 USPQ 645, 648 (Fed. Cir. 1985). Applicants respectfully submit that issuance of the claims of the instant application will not result in a time-wise extension of a patent for the same invention. The claims of the instant application are patentable distinct from those of the '764 patent. The compounds claimed in the instant application are distinct from those claimed in the '764 patent claims. Accordingly, applicants are not receiving an extension of the claimed subject matter in the '764 patent by issuance of the claims of the instant

application.

Applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claim 1-37 under obviousness-type-double patenting in view of the claims of the '764 patent.

II. New Rejection under 35 U.S.C. §103(a)

The Examiner on page 5 of the May 5, 2003 Office Action issued a new rejection of the claims under 35 U.S.C. §103(a) as allegedly being unpatentable over Larson et al. (U.S. Pat. No. 6,235,764 B1). The Examiner applied some of the factors set forth in *Graham v. John Deere Co.*, 148 USPQ 459 (1966) to support her rejection on pages 5 and 6 of the Action. Applicants respectfully traverse the Examiner's rejection of the claims of the instant application under 35 U.S.C. §103(a), in view of Larson et al., for the following reasons.

Applicants respectfully submit that the Examiner is improperly applying Larson et al. against the instant invention in contravention of 35 U.S.C. §103(c). Applicants direct the Examiner's attention to MPEP §706.02(k) excerpted below for the Examiner's convenience.

Effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person **or subject to an obligation of assignment to the same person.**" (Emphasis added). This change to 35 U.S.C. 103(c) applies to all utility, design and plant patent applications filed on or after November 29, 1999, including continuing applications filed under 37 CFR 1.53 (b), continued prosecution applications filed under 37 CFR 1.53 (d), and reissues. The amendment to 35 U.S.C. 103(c) does not affect any application filed before November 29, 1999, a request for examination under 37 CFR 1.129 of such an application, nor a request for continued examination under 37 CFR 1.114 of such an application. The changes to 35 U.S.C.

Patent Application
Attorney Docket No. PC11042A
United States Patent Application No. 09/993,640

102(e) in the Intellectual Property and High Technology Technical Amendments Act of 2002 (Pub. L. 107-273, 116 Stat. 1758 (2002)) did not affect the exclusion under 35 U.S.C. 103(c) as amended on November 29, 1999. See MPEP §706.02(l)(1) for additional information regarding disqualified prior art under 35 U.S.C. 102 (e)/103.

Applicants respectfully submit that Larson et al. qualifies as prior art to the instant application under 35 U.S.C. §102(e). Applicants note that the 35 U.S.C. §102(a) and 35 U.S.C. §102(b) date for the Larson et al. is its publication date as a patent on May 22, 2001. The instant application predates the Larson et al. the 35 U.S.C. §102(a) and 35 U.S.C. §102(b) date by almost 6 months, i.e., earliest effective filing date of the instant application is November 28, 2000. Therefore, Larson et al. does not qualify as prior art to the instant application under 35 U.S.C. §102(a) and 35 U.S.C. §102(b).

With respect to 35 U.S.C. §102(e), as recited in MPEP §706.02(k), section 102(e) has been added to the common ownership prior art disqualifier in 35 U.S.C. §103(c). Applicants respectfully submit that the instant application and the issued Larson et al. patent are subject to an obligation of assignment to the same person, i.e., Pfizer Inc. Accordingly, Larson et al. does not qualify to be applied against the instant application in a 35 U.S.C. §103(a) rejection due to the exemption provided for commonly owned prior art under 35 U.S.C. §102(e) in 35 U.S.C. §103(c). Accordingly, applicants' respectfully request the Examiner to reconsider the application of the 35 U.S.C. §103(a) rejection in view of the preceding remarks.

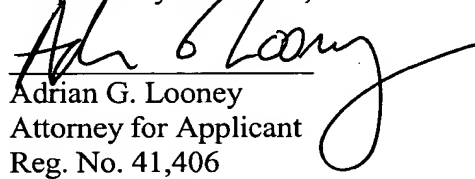
Patent Application
Attorney Docket No. PC11042A
United States Patent Application No. 09/993,640

CONCLUSION

For the reasons set forth hereinabove, applicants respectfully request that the Examiner reconsider and her rejections set forth in the May 5, 2003 Office Action and earnestly solicit allowance of the claims pending in the subject application. Applicants' undersigned attorney may be reached at the phone number listed below if the Examiner believes that this will help advance prosecution and allowance of the subject application.

Date: Nov 5, 2003

Respectfully submitted,


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